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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,360	01/16/2001	Wolfgang Halfbrodt	SCH-1738	1922

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EXAMINER
ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
1625	9

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/759,360	Applicant(s) HALFBRODT ET AL.	
	Examiner Binta M. Robinson	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

The applicant's election of species has been noted at paper no. 7/B. The election of species will be used as a reference point for the examiner to create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence and restriction will be required under 35 U. S. C. 121.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-26, drawn to a compound of formula I where R1 and R2 equal optionally substituted phenyl, where the substituents on R1 and R2 do not come together to form a ring, R3 is as claimed and does not come together with another R3 to form a ring, R4, and R4', R5 and R5', are all moieties claimed except heterocyclic or heteroaryl rings, A are moieties claimed except a heterocyclic ring, B are all moieties claimed except tetrazolyl, X is as claimed, Y is as claimed, a method of treating a patient, a process of preparing a pharmaceutical composition, a pharmaceutical composition, classified in class 514, subclass 394.

II. Claims 1-26, drawn to a compound of formula I in claim 1 where R1, R2, R4, R4', R5, R5', B, are all other substituents not claimed in group I, and R3, X, and Y are as claimed, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

In the instant case the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under

35 USC 102(b) would not render obvious the same claim(s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

By virtue of the applicant's election of species which falls into group I, group I will be examined. If group II is prosecuted further in a divisional application, it may be subject to further restriction requirements.

The unelected portions of claims 1-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-26 in part are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the radicals R1, R2, R5, and R5' coming together to form all possible 5-10 membered heteroaryl groups with 1-4

heteroatoms selected from N, S, or O, R4 and R4' coming together to form all C1-3 alkyl- 5-10 membered heteroaryl rings with 1-4 N, S, or O atoms or 5 to 10 membered heteroaryl rings with 1-4 N, S, or O atoms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

The specification does not enable the treating or prevention of all diseases with a compound of claim 1 as claimed in claim 13. It is also not established in the art to prevent diseases with drugs as claimed in claim 13. Claim(s) 15 in part are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Microglia activation is a mechanism. The specific disease being treated by this inhibition is not stated. The specification must contain one practical utility in currently available form. Microglia activation must be related to a disease that needs to be improved and this disease needs to be recited. There is no reasonable assurance that these compounds will have all of the alleged properties or have the applicants

supplied the supporting data. The applicant is referred to ***In re F uch*** 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte Foreman*** 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of factor 3 and 5, the state of the art and the level of predictability in the art cannot be predicted with any certainty beyond what specific test compounds /compositions and/or additional therapeutic agents should be used and are likely to provide productive results beyond those therapeutic compounds/compositions and/or additional therapeutic agents taught in the specification. Only example 307 was tested for its affect on microglial activation, 308 for its affect on cerebral ischmia, permanent middle cerebral artery occlusion, and 309 was tested for its affects on machrophage activation.

In terms of factors 4 and 6, the inventor provides no guidance beyond the therapeutic compound/compositions and/or therapeutic agents as taught in the specification as previously mentioned. As a result one of ordinary skill in the art could not predict what other types of therapeutic compounds/compositions and/or additional therapeutic agents, other than those taught in the specification; and with regards to the 7th and 8th wands factor, while the existence of working examples are limited to the aforementioned compounds/compositions as taught in the specification (example 307-309), an indeterminate quantity of experimentation would be necessary to determine all potential therapeutic compounds/compositions' effects on microglia activation.

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim(s) 3-10,13, 15 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 3-10 in part, line 1, pages 1-4 of the preliminary amendment at paper no. 4, the term "benzimidazoles" is indefinite. It is unclear as to whether or not a pharmaceutical

composition is being claimed or a compound. The term "A compound" is suggested if a compound is being claimed.

B. In claim 13, line 2, page 6 of the amendment and election at paper no. 7, the term "diseases" is indefinite. Which diseases are the applicant claiming?

C. In claim 15, lines 2-3, page 6 of the amendment at paper no. 7, the phrase "disease associated with microglia activation" is indefinite. Which specific disease is the applicant claiming?

D. In claim 1, the phrase "wherein two of said R1 substituents", on line 13, page 2 of the amendment at paper no. 7, the phrase "wherein two of said R2 substituents" , on page 2 of the amendment at paper no. 7, the phrase "wherein two substituents R3" on page 3 of the amendment at paper no. 7, are indefinite. There is only one R1 substituent, one R2 substituent, and one R3 substituent depicted in the compound of formula I in claim 1. So how can two R1 substituents come together to form a ring for example?

The elected species appears to be allowable.

The IDS filed at paper no. 8 has been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson

June 17, 2002

ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
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